Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / *Certificate No* : 45-20-01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 25.09.2020-25.09.2025
Belge Geçerlilik Tarihi / *Document Validity Period* : 5 yıl / ***5 years***
Firma Unvanı ve Adresi /
Company Name and Address : MY TİCARET VE MEDİKAL A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad. No: 33 Arnavutköy/ İSTANBUL

Ürün Adı /Modeller / *Product Name / Models* : Mumu Plus MN01
Mumu MN01
Simplistic By Mumu MN01

Direktifi / *Directive* : 2016/425 REGULATION
Modülü/Kategori / *Module / Category* : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III

Test Rapor No/ları / *Test Report No* : MNA M-2020-00308
Ürün Tipi / *Product Type:*

- EN 420 Koruyucu Eldivenler / *Protective gloves*
- EN ISO 374-1 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler (Performans Seviyeleri: Tip C) / *Protective Gloves Against Dangerous Chemicals And Micro-Organisms (Performance Level: Type C)*
- EN ISO 374-5 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler - Bölüm 5: Mikroorganizmal riskler için terimler ve performans kuralları / *Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks*

Ürünün Malzeme Bilgisi / *Product Material Information*: MN01 model ürünleri sentetik nitril kullanılarak imal edilmiştir./ MN01 *model products are manufactured using synthetic nitrile.*

Volkan AKIN	***Okan AKEL***
25.09.2020	***25.09.2020***
Karar Verici / Approver	***Şirket Müdürü / General manager***

Notified Body Number: 2841

ATTACHMENTS (45-20-01)

Model : MN01

PPE SPECIFICATION	PERFORMANCE LEVELS
Ability	5
Material Resistance To Permeation By Chemicals	2 (Type C)
Phi-X174 Bacteriophage	Appropriate

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

PRODUCT SIZE: XS, S, M, L, XL

MARKING

COMPANY: MY TİCARET VE MEDİKAL A.Ş.
PPE TYPE:

- EN 420+ A1 Protective gloves
- EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms
- EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

PRODUCT SIZE / MODEL: MN01 (XS, S, M, L, XL)
PICTOGRAM AND PERFORMANCE LEVELS:

	EN 420+A1	EN ISO 374-1/2016 Type C	EN ISO 374-5/2016
NB 2841		K	VIRUS

MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

PRODUCT PICTURES
MN01 (Blue, Violet Blue, Black, Purple, White)

DOCUMENTS IN THE TECHNICAL FILE
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Review Reports - Technical Report

MY Medikal

EU DECLARATION OF CONFORMITY

Company Name	**:MY TİCARET VE MEDİKAL A.Ş.**
Company Address	:Ömerli Mah. General Şükrü Koraltı Cad. No:33 Arnavutköy, İstanbul/TURKEY

EXAMINATION AND PROTECTIVE GLOVES

Name of Device	:Nitrile Examination Gloves
Type	:Powder Free
Classification	:PPE Category III
Brand	:Mumu-Mumu Plus-Simplistic by mumu
Model	:MN01

It complies with the provisions of the EU Regulation 2016/425 –Cat III of March 9, 2016 and, in particular, with the specifications of the harmonized standards: EN 420:2003+A1:2009 and EN ISO 374-1:2016/A1:2018 EN ISO 374-5:2016 edited by the European Committee for Standardization.

The Notified Body **MNA LABORATUVARLARI SANAYI TICARET LIMITED**, notified body **n°2841**, in Kucukbakkalkoy Mah. Yenidogan Cad., No:21 Atasehir/Istanbul/Turkey, has carried out the EU type examination (module C2) and has issued **the EU type 45-20-01** certificate.

Date :25.09.2025

Sign : MURAT YILDIZ

MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İSTANBUL
Büyükçekmece V.D.: 626 040 4605
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CE 2841

MY TİCARET VE MEDİKAL A.Ş
Ömerli Mah. General Şükrü Koraltı Cad. No:33 Arnavutköy / İstanbul / TURKEY
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info@mymedikal.com.tr **www.mymedikal.com.tr**

NAC

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

This is to certify that

Quality Management System

of

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

ÖMERLİ MAHALLESİ GENERAL ŞÜKRÜ KORALTI CAD. NO: 33
ARNAVUTKÖY - İSTANBUL / TÜRKİYE

complies with requirements of

ISO 9001:2015

This certificate is valid concerning all activities related to;

PRODUCTION AND SALE OF LATEX POWDERED / POWDER FREE EXAMINATION GLOVES, NITRILE POWDER FREE EXAMINATION GLOVES, STERIL / NON-STERILE SURGICAL GLOVES, STERIL / NON-STERILE SPONGE GAUZE COMPRESS, STERIL / NON-STERIL COMPRESSE ABDOMINALE, STERIL / NON-STERILE COTTON PAD, GAUZE, STERILE / NON-STERILE SURGICAL MASK

LATEKS PUDRALI / PUDRASIZ MUAYENE ELDiVENi, NiTRiL PUDRASIZ MUAYENE ELDiVENi, STERiL / NON-STERiL CERRAHi ELDiVEN, STERiL / NON-STERiL SPANÇ GAZ KOMPRES, STERiL / NON-STERiL BATIN KOMPRES, STERiL / NON-STERiL PAMUKLU PED, GAZLI BEZ,
STERiL / NON-STERiL CERRAHi MASKE ÜRETİMİ VE SATIŞI

ISO 01 940 1179 *Certificate No.*	Jun. 5, 2020 *Date of this Certificate*	Jun. 4, 2021 *Certification Expiry Date*
May. 28, 2020 *Date of Audit*	Jun. 5, 2020 *Date of Registration*	*Managing Director / Director*

MDC
MEDICERT CERTIFICATE

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

* You can query the validity of this certificate by sending an e-mail to info@medicert.com.tr.

Certificate of Registration

This is to certify that

Quality Management System

for Medical Devices

of

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

ÖMERLİ MAHALLESİ GENERAL ŞÜKRÜ KORALTI CAD. NO: 33
ARNAVUTKÖY - İSTANBUL / TÜRKİYE

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to;

SALES OF LATEX POWDERED / POWDER-FREE EXAMINATION GLOVES- NITRILE POWDER-FREE EXAMINATION GLOVES- POWDERED / POWDER-FREE STERILE SURGICAL GLOVES-VINYL POWDERED / POWDER-FREE EXAMINATION GLOVES. PRODUCTION AND SALE OF DISPOSABLE NON-STERILE MASKS.

LATEKS PUDRALI/PUDRASIZ MUAYENE ELDİVENİ- NİTRİL PUDRASIZ MUAYENE ELDİVENİ- PUDRALI/PUDRASIZ STERİL CERRAHİ ELDİVEN-VİNİL PUDRALI/PUDRASIZ MUAYENE ELDİVENİ SATIŞI. TEK KULLANIMLIK NON-STERİL MASKE ÜRETİMİ VE SATIŞI.

ISO 02 836 1179 *Certificate No.*	Feb. 26, 2020 *Date of this Certificate*	Feb. 25, 2021 *Certification Expiry Date*
Feb. 21, 2020 *Date of Audit*	Feb. 26, 2020 *Date of Registration*	*Managing Director / Director*

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

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Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T

M-2020-00308

25.09.2020

MNA LABORATORIES
TEST REPORT

Report No: M-2020-00308	Date: 25.09.2020	Page: 1 / 3	Rev:

Purpose of Analysis : SPECIAL REQUEST
Sample Type : NITRILE PROTECTIVE GLOVE
Sample Send Org. : MY TİCARET VE MEDİKAL A.Ş
Manufacturer Name : MY TİCARET VE MEDİKAL A.Ş
Analysis Date : 16.09.2020
Sample Quantity : 40 pieces
Other informations : NITRILE EXAMINATION GLOVE

Brand : Mumu Plus, Mumu, Simplistic By Mumu
Model : MN01
Sampler : CUSTOMER

No	Tests	Results	Limit Value	Method	Evaluation	Physical Condition
1	Dexterity *	5 (mm)	5 mm	TS EN 420 + A1 Part 6.2	PERFORMANCE LEVEL:5	
2	Determination of material resistance to permeation by chemicals *	30min no permeation. (%40NaOH) (ug/cm².min)	>30 min	TS EN 16523-1	PERFORMANCE LEVEL:2	
3	Determination of Phthalates	<50 (mg/kg)	<1000 ppm	ISO/TS 16181	PASS	
4	Penetration By Blood-Borne Pathogens(Bacteriophage)	0 (PFU/ml)	3,5 kPa	BS ISO 16604	PERFORMANCE LEVEL:3	
5		0 (PFU/ml)	3,5 kPa	BS ISO 16604		
6		0 (PFU/ml)	3,5 kPa	BS ISO 16604		
7	Determination of pH *	7,77	3.5 < Result < 9.5	EN 420 + A1 Part 4.3.2 TS EN ISO 3071	PASS	
8	Air leak test *	0,5 kPa no leak.	Should be no leak	TS EN 374-2 Part 5.2	PASS	
9	Water leak test *	No leak.	Should be no leak	TS EN 374-2 Part 5.3	PASS	
10	Determination of resistance to degradation by chemicals *	63,84 (ACETONE) (%)	-	TS EN 374-4	-	
11	Determination of material resistance to permeation by chemicals *	2 min permeation seen.(%96 H2SO4) (ug/cm².min)	> 10 min	TS EN 16523-1	PERFORMANCE LEVEL:X	
12		4,59 min permeation seen. METHANOL (ug/cm².min)	>30 min	TS EN 16523-1	PERFORMANCE LEVEL:X	
13	Sizing and measurement of gloves *	251 (mm)	≥ 250 mm < 260 mm	TS EN 420 + A1 Part 6.1	PASS	
		Length 192 (mm)		TS EN 420 + A1 Part 6.1	-	

FRM:23/rev.02/09.08.2019

Küçükbakkalköy Mahallesi Yenidogan Caddesi No: 21 Atasehir İstanbul
info@mnalab.com tel: 02165740708 faks: 02165751331

Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T
M-2020-00308
25.09.2020

MNA LABORATORIES
TEST REPORT

Report No: M-2020-00308	Date: 25.09.2020	Page: 2 / 3	Rev:

Purpose of Analysis	: SPECIAL REQUEST	**Brand**	: Mumu Plus, Mumu, Simplistic By Mumu
Sample Type	: NITRILE PROTECTIVE GLOVE	**Model**	: MN01
Sample Send Org.	: MY TİCARET VE MEDİKAL A.Ş	**Sampler**	: CUSTOMER
Manufacturer Name	: MY TİCARET VE MEDİKAL A.Ş		
Analysis Date	: 16.09.2020		
Sample Quantity	: 40 pieces		
Other informations	: NITRILE EXAMINATION GLOVE		

13	Sizing and measurement of gloves *	Circumference	172 (mm)		TS EN 420 + A1 Part 6.1	-	

Sample Place
13. Line Sample place for Sizing and measurement of gloves: Size: 9
1. Line Sample place for Dexterity: Size: 9

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info@mnalab.com tel: 02165740708 faks: 02165751331

Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T
M-2020-00308
25.09.2020

MNA LABORATORIES
TEST REPORT

Report No: M-2020-00308	Date: 25.09.2020	Page: 3 / 3	Rev:

Purpose of Analysis	: SPECIAL REQUEST	**Brand**	: Mumu Plus, Mumu, Simplistic By Mumu
Sample Type	: NITRILE PROTECTIVE GLOVE	**Model**	: MN01
Sample Send Org.	: MY TİCARET VE MEDİKAL A.Ş	**Sampler**	: CUSTOMER
Manufacturer Name	: MY TİCARET VE MEDİKAL A.Ş		
Analysis Date	: 16.09.2020		
Sample Quantity	: 40 pieces		
Other informations	: NITRILE EXAMINATION GLOVE		

Operating as an experimental laboratory, MNA Laboratories have been accredited by TURKAK with AB-1183-T and TS_EN_ISO / IEC_17025: 2017 standard. Turkish Accreditation Agency (TÜRKAK) signed a multilateral agreement with the European Accreditation Association (EA) on the recognition of test reports and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).
*** Analysis is under accreditation.**

Note :

1. No part of this analysis report can be used alone or separately, and may not be partially copied or reproduced, used to third parties and as a means of advertising without the written permission of the laboratory.
2. Analysis results are valid for the above mentioned sample sent by MNA Laboratory company / institution / person. It may not represent the whole.
3. Unsigned and unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative procedures and for advertising purposes.
5. Results are valid for the sample as received.
6. The decision rule is the rule that determines how measurement uncertainty is taken into account when specifying the PASS density to a specified specification. According to the TLM-052 Decision Rule Implementation instruction, the Decision Rule Implementation Method selected in agreement with CUSTOMER is clearly stated in the report.
7. Limit Values are determined by taking from analysis methods.
8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.
10. Water Repellency Determination Hydrostatic Pressure Determination TS ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and 50 ± 4% relative humidity) are applied for ambient conditions.
11. List of phthalates analyzed is below.
Di-iso-nonyl phthalate (DINP), CAS number: 28553-12-0 or 68515-48-0
Di- (2-ethylhexyl) phthalate (DEHP), CAS number: 117-81-7
Di-n-octyl phthalate (DNOP), CAS number: 117-84-0
Di-iso-decyl phthalate (DIDP), CAS number: 26761-40-0 or 68515-49-1
Butyl benzyl phthalate (BBP), CAS number: 85-68-7
Di-butyl phthalate (DBP), CAS number: 84-74-2

Selin GERGİN
Sampling and Reporting Officer

Erhan ÜSTÜNEL
PPE Laboratory Responsible

Approval
25.09.2020
Volkan AKIN
Laboratory Manager

Küçükbakkalköy Mahallesi Yenidogan Caddesi No: 21 Atasehir İstanbul
info@mnalab.com tel: 02165740708 faks: 02165751331

EUROLAB® Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2020240701

Report No:	2020240701 – R1
Applicant:	**MY TİCARET VE MEDİKAL A.Ş** Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Contact Person:	Z.Melek ÖZ BOLAT
Contact Telephone:	+90 212 438 20 64
Contact e-mail:	kalite@mymedikal.com.tr
Sample Accepted on:	03.07.2020
Report Date:	24.07.2020
Total number of pages:	6(Pg)

Sample ID: **NITRILE EXAMINATION GLOVE / LATEX EXAMINATION GLOVE**

	TEST	METHOD	Specimen	RESULT
*	Medical Gloves For Single Use Part 1: Requirments And Testing For Freedom From Holes	EN 455-1	Nitrile Examination Glove	PASS
			Latex Examination Glove	PASS
*	Medical Gloves For Single Use Part 2: Requirements And Testing For Physical Properties	EN 455-2	Nitrile Examination Glove	PASS
			Latex Examination Glove	PASS

Seal

Customer Representative
Hasan KUTLU

Laboratory Manager
Hava SARIAYDIN

PR33-F01/08.10.2015/Rev:17.01.2017-R01

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Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

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EN 455-1

Medical Gloves For Single Use Part 1: Requirments And Testing For Freedom From Holes

Scope;

This part of this standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

Test Method;

Fill vertically so that the glove fits in size and the pipe can hold any of the 1000 ml of water that can exceed the glove's natural filling volume.

Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove.

Add 1 000 ml ± 50 ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove.

NOTE Some of the water may remain in the filling tube depending on the glove being tested.

Immediately inspect the glove visually for water leakage. Allow the glove to hang and visually inspect the glove for water leakage again afler a period of 2 min to 3 min.

If, because of distension of the glove, the water does not rise to within 40 mm of the cuff end, raise the glove after the second inspection by a suilable means until the water level reaches 40 mm from the cuff end. Inspect visually the previously untested portion of the glove after a further period of 2 min to 3 min. Disregard leakages within 40 mm of the cuff.

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number: MN01**
	Latex Examination Glove Catalog Number: MLP/MLPF-02
Color	**Blue, White**

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TEST RESULTS

	Test	Result	Overal Rating
Dimensions	15-35°C 1000 ml, 50ml Water	No Leakage	PASS
Test 2	15-35°C 1000 ml, 50ml Water	No Leakage	
Test 3	15-35°C 1000 ml, 50ml Water	No Leakage	

Conclusion: There is no water leakage in the Glove, the test is successful.

EN 455-2

Medical Gloves For Single Use Part 2: Requirements And Testing For Physical Properties

Scope;

This standard specifies requirements and gives test methods for pyhsical properties for single use medical (is surgical gloves and examination/procedure gloves) in order to ensure that they provice and maintain in use an adequate level of protection from cross contamination for both patient and user.

Product	**Medical Glove**
Brand	**Mumu - Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number: MN01** **Latex Examination Glove Catalog Number: MLP/MLPF-02**
Color	**Blue, White**

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TEST RESULTS

	Result	Overal Rating
Dimensions	≥ 240 mm (and 295 ± 5 mm for long) Extra-Small: 75 5 mm - Small: 80 10 mm - Medium: 95 10 mm Large: 110 10 mm - Extra-Large: ≥ 110	PASS
Tensile Strength	≥ 6,0 Newton	
Breaking force after the tensile strength test	≥ 6,0 Newton	

Conclusion: Meet EN 455-2 reqirements Glove, the test is successful.

EN 455-4

Medical gloves for single use Part 4: Requirements and testing for shelf life determination

This part of EN 455 specifies requirements for shelf life for medical gloves for single use. It also specifies therequirements for labelling and the disclosure of information relevant to the test methods used

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number: MN01** **Latex Examination Glove Catalog Number: MLP/MLPF-02**
Color	**Blue, White**

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Image

*****END OF REPORT*****

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EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2020190876

Report No: 2020190876
Applicant: **MY TİCARET VE MEDİKAL A.Ş**
Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Contact Person: Z.Melek ÖZ BOLAT
Contact Telephone: +90 212 438 20 64
Contact e-mail: kalite@mymedikal.com.tr
Sample Accepted on: 03.07.2020
Report Date: 19.08.2020
Total number of pages: 24 (Pg)

Sample ID: **NITRILE EXAMINATION GLOVE/ LATEX EXAMINATION GLOVE**

	TEST	METHOD	Specimen	RESULT
*	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	EN 455-3	Nitrile Examination Glove	PASS
			Latex Examination Glove	PASS
*	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	EN 455-4	Nitrile Examination Glove	PASS
			Latex Examination Glove	PASS
*	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1	Nitrile Examination Glove	PASS
			Latex Examination Glove	PASS

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş. TÜRCERT

Seal

Customer Representative
Hasan KUTLU

EUROLABORATUVAR HİZMETLERİ TÜRCERT

Laboratory Manager
Hava SARIAYDIN

PR33-F01/08.10.2015/Rev:17.01.2017-R01

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Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

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EN 455-3 Medical Gloves For Single Use - Part 3: Requirements And Testing For Biological Evaluation

Scope:

This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.

TEST METHODS

Endotoxins

The outside surface of a pair of gloves is extracted with 40 ml of endotoxin-free water (Water LAL, European Pharmacopoeia, for not less than 40 min and not more than 60 min at a temperature between 37 °C and 40 °C in a way to ensure that all surfaces come into contact with the extraction medium. The extract is centrifuged, if necessary, for 15 min at 2000 g to remove particles after which the liquid component is decanted and tested for endotoxin immediately afterwards.

Powder

This International Standard specifies methods for the determination of readily removable powder on the surface of gloves for medical use. Three methods are specified: method A for powdered gloves and methods B and C for powder-free gloves.

Procedure:

The surfaces of a glove are washed with water to remove the water-insoluble powder which is then determined by filtration followed by weighing.

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Proteins, Leachable

This method is for the determination of the amount of aqueous extractable proteins in gloves for medical use made from natural rubber (NR). It has been validated during inter-laboratory round-robin tests. The lower quantification limit is approximately 10 µg protein per g of glove (i.e. 2 µg protein per ml of extract) depending on the glove weight.

Procedure:

Water soluble proteins are extracted into a buffer solution and then precipitated with acids in the presence of sodium deoxycholate to concentrate them and to separate them from water soluble substances which may interfere with the determination. The precipitated proteins are redissolved in alkali and quantified colorimetrically by a modified Lowry method. The assay is based on the reaction of proteins with copper and Folin reagent in an alkaline medium to give a characteristic blue colour. Spectrophotometric measurements are performed at a fixed wavelength in the range 600 nm to 750 nm.

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number: MN01** **Latex Examination Glove Catalog Number: MLP/MLPF-02**
Color	**Blue / White**

TEST RESULTS

Endotoxins

Specimen	Endotoxin Requirement (EU)	Result
Nitrile Examination Glove	<20	PASS
Latex Examination Glove	<20	PASS

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Powder

Specimen	Powder Value (mg)	Result
Nitrile Examination Glove	<2 mg	PASS
Latex Examination Glove	<2 mg	PASS

Proteins, Leachable

Specimen	Protein value (µg)	Result
Nitrile Examination Glove	<30 µg	PASS
Latex Examination Glove	<30 µg	PASS

EN 455-4 Medical Gloves For Single Use - Part 4: Requirements And Testing For Shelf Life Determination

Scope:

This part of EN 455 specifies requirements for shelf life for medical gloves for single use. It also specifies the requirements for labelling and the disclosure of information relevant to the test methods used.

Real time shelf life determination

Gloves in consumer packages are conditioned at the temperature as defined by the manufacturer (e.g. 25 °C) for the intended shelf life period and then tested for compliance

Upon completion of the procedure, the shelf-life claim will be up to this time, not exceeding five years that the gloves are in compliance with the requirements of this European Standard.

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Accelerated shelf life determination

Because of the errors and uncertainties inherent in the determination of shelf lives using accelerated ageing methods shelf life claims should be limited to a maximum of 3 years.

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number: MN01**
	Latex Examination Glove Catalog Number: MLP/MLPF-02
Color	**Blue / White**

TEST RESULTS

Real time shelf life determination

Test Item: Rapid Aging Test-Xenon-ark
Exposure Sample Description: Nitrile Examination Glove , Latex Examination Glove

Test Condition:

Exposure cycle

Irradiation: (0,50 ± 0,2) W /(m2-nm)@340nm 1080 h
Filter: Daylight - UV-B / UV-A / UV-C - KSENON ARK
Exposure time: 1080 hours

Test	UVA Exposure Time	Gray Scale	Customer Requirement	Result
1	1080 h	5-5	-	PASS

Observation ;
Nitrile Examination Glove is resistant to Latex Examination Glove 1080 hours UV aging.

UV AGING

The molecular structure of the samples was examined by FTIR (Mattson) before and after this test.

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UV AGING

The molecular structure of the samples was examined by FTIR (Mattson) before and after this test.

Conclusion: When adequate protection is not provided, radical formation, chain breakage and carbonyl formation did not occur in the structure of raw materials with the effect of UV, with the contribution of air oxygen.

During the test, normal daily conditions targeted at 25 ° C for 1080 hours were simulated and no color change and deterioration were observed.

Measurement Device	Rates	Date of Calibration
EUROLAB EL / UV IR VL Xenon	UVA-UVB (290 to 315 nm)	03.11.2019

In the test environment, the relative Humidity is 50% in the environment.
In the test environment, the air temperature is about 25 degrees centigrade.

Accelerated shelf life determination

Test Item: Rapid Aging Test-Xenon-ark
Exposure Sample Description: Nitrile Examination Glove , Latex Examination Glove

Test Condition:

Exposure cycle

Irradiation: (0,50 ± 0,2) W /(m2-nm)@340nm 720 h
Filter: Daylight - UV-B / UV-A / UV-C - KSENON ARK
Exposure time: 720 hours

Test	UVA Exposure Time	Gray Scale	Customer Requirement	Result
1	720 h	5-5	-	PASS

Observation ;

Nitrile Examination Glove is resistant to Latex Examination Glove 720 hours UV aging.

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UV AGING

The molecular structure of the samples was examined by FTIR (Mattson) before and after this test.

Conclusion: When adequate protection is not provided, radical formation, chain breakage and carbonyl formation did not occur in the structure of raw materials with the effect of UV, with the contribution of air oxygen.

During the test, normal daily conditions targeted at 25 ° C for 720 hours were simulated and no color change and deterioration were observed.

Measurement Device	Rates	Date of Calibration
EUROLAB EL / UV IR VL Xenon	UVA-UVB (290 to 315 nm)	03.11.2019

In the test environment, the relative Humidity is 50% in the environment.
In the test environment, the air temperature is about 25 degrees centigrade.

TS EN ISO 10993-1

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

This part of ISO 10993 describes: the general principles governing the biological evaluation of medical devices within a risk management process; the general categorization of devices based on the nature and duration of their contact with the body; the evaluation of existing relevant data from all sources; the identification of gaps in the available data set on the basis of a risk analysis; the identification of additional data sets necessary to analyse the biological safety of the medical device; the assessment of the biological safety of the medical device.

Cytotoxicity

Cytotoxicity tests employing cell culture techniques shall be used to determine the lysis of cells (cell death), the inhibition of cell growth, colony formation, and other effects on cells caused by medical devices, materials and/or their extracts (see ISO 10993-5).

Delayed-type hypersensitivity

Hypersensitivity tests shall be used to estimate the potential for contact sensitization by medical devices, materials and/or their extracts, using an appropriate animal model (see ISO 10993-10).

These tests are important because exposure or contact to even minute amounts of potential leachables can result in allergic or sensitization reactions.

Irritation (including intracutaneous reactivity)

Irritation tests shall be used to estimate the irritation potential of medical devices, materials and/or their extracts, using an appropriate site for application such as skin, eye and mucous membrane in a suitable model. The test(s) performed shall

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be appropriate for the route (skin, eye, mucosa) and duration of exposure or contact (see ISO 10993-10).

The intracutaneous reactivity test shall be used to assess the localized reaction of tissue to medical device extracts. This test is applicable where the determination of irritation by dermal or mucosal tests is inappropriate (e.g. where medical devices are implanted or have blood contact).

This test might also be useful where extractables are hydrophobic (see ISO 10993-10).

Systemic toxicity (acute)

Acute systemic toxicity tests shall be used where contact allows potential absorption of toxic leachables and degradation products, to estimate the potential harmful effects of either single or multiple exposures, during a period of less than 24 h, to medical devices, materials and/or their extracts in an animal model (see ISO 10993-11).

Pyrogenicity tests are included to detect material-mediated pyrogenic reactions of extracts of medical devices or materials. No single test can differentiate pyrogenic reactions that are material-mediated from those due to endotoxin contamination.

If feasible, acute systemic toxicity tests may be combined with subacute and subchronic toxicity and implantation test protocols.

Subacute and subchronic toxicity

Subacute and subchronic toxicity tests shall be carried out to determine the effects of either single or multiple exposures or contact to medical devices, materials and/or their extracts for a period not less than 24 h to a period not greater than 10 % of the total life-span of the test animal (e.g. up to 13 weeks in rats).

These tests shall be waived if available data for the chronic toxicity of the relevant materials are sufficient to allow the subacute and subchronic toxicity to be evaluated. The reason for waiving of the tests shall be included in the overall biological evaluation report. These tests shall be appropriate for the route and duration of contact.

Subacute and subchronic toxicity tests are given in ISO 10993-11.

If feasible, subacute and subchronic systemic toxicity test protocols may be expanded to include implantation test protocols to evaluate subacute and subchronic systemic and local effects.

Genotoxicity

A battery of *in vitro* genotoxicity tests employing mammalian or non-mammalian cell culture or other techniques shall be used to determine gene mutations, changes in chromosome structure and number, and other DNA or gene toxicities caused by medical devices, materials and/or their extracts.

If any of the *in vitro* tests are positive, either *in vivo* mutagenicity tests shall be performed or the presumption shall be made that the material is mutagenic (see ISO 10993-3).

Implantation

Implantation tests shall be used to assess the local pathological effects on living tissue, at both the gross level and microscopic level, of a sample of a material or final product that is surgically implanted or placed in an implant site or tissue appropriate to the intended application (e.g. special dental usage tests). These tests shall be appropriate for the route and duration of contact.

If feasible, implantation test protocols may be expanded to evaluate both local and systemic effects to meet acute, subacute, subchronic, and chronic toxicity testing requirements (see ISO 10993-6).

Haemocompatibility

Haemocompatibility tests shall be used to evaluate, using an appropriate model or system, the effects of blood-contacting

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medical devices or materials on blood or blood components.

One haemocompatibility test, haemolysis, determines the degree of red cell lysis and the release of haemoglobin caused by medical devices, materials, and/or their extracts *in vitro*.

Other specific haemocompatibility tests may also be designed to simulate the geometry, contact conditions and flow dynamics of the device or material during clinical applications and determine blood/material/device interactions (see ISO 10993-4).

Chronic toxicity

Chronic toxicity tests shall be used to determine the effects of either single or multiple exposures to medical devices, materials and/or their extracts during a major period of the life-span of the test animal (e.g. usually 6 months in rats). These tests shall be appropriate for the route and duration of exposure or contact (see ISO 10993-11).

If feasible, chronic systemic toxicity test protocol may be expanded to include an implantation test protocol to evaluate both chronic systemic and local effects.

Carcinogenicity

If there is no information from other sources, testing the potential carcinogenicity of the material/device shall be considered. However, it is rare for carcinogenicity tests to be considered appropriate for medical devices (see ISO 10993-3). Carcinogenicity tests shall be used to determine the tumorigenic potential of medical devices, materials and/or their extracts from either single or multiple exposures or contacts over a period of the major portion of life-span of the test animal. Carcinogenicity tests should be appropriate for the route and duration of exposure or contact; lifetime studies or transgenic models may be appropriate. These tests may be designed to examine both chronic toxicity and tumorigenicity in a single experimental study.

Reproductive and developmental toxicity

Reproductive and developmental toxicity tests shall be used to evaluate the potential effects of medical devices, materials and/or their extracts on reproductive function, embryonic development (teratogenicity), and prenatal and early postnatal development. Reproductive/developmental toxicity tests or bio-assays shall only be conducted when the device has potential impact on the reproductive potential of the subject. In addition, such tests should be considered for devices/materials used during pregnancy. The application site of the device is the primary criterion when considering carrying out the tests. Reproductive and developmental toxicity tests are described in ISO 10993-3.

Biodegradation

Biodegradation tests shall be considered if

a) the device is designed to be biodegradable

or

b) the device is intended to be implanted for longer than 30 d

or

c) an informed consideration of the material(s) system indicates that toxic substances might be released during body contact.

Parameters that affect the rate of degradation shall be described and documented.

The mechanisms of biodegradation should be described. These mechanisms should be simulated *in vitro* to determine the rates of degradation and release of potentially toxic chemicals to estimate the exposure. *In vivo* tests may be required to assess biodegradation of a material.

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Biodegradation tests might not be necessary if the probable products of degradation are in the predicted quantities, and produced at a rate similar to those that have a history of safe clinical use; and/or if particulate, they are present in a physical state, i.e. size distribution and shape, similar to those with a history of safe clinical use or sufficient degradation data relevant to the substances and degradation products in the intended use already exists.

A general framework for biodegradation tests is given in ISO 10993-9.

Specific *in vitro* biodegradation tests for polymers, ceramics and metals are described in ISO 10993-13, ISO 10993-14 and ISO 10993-15 respectively.

Toxicokinetic studies

The purpose of conducting toxicokinetic studies is to evaluate the absorption, distribution, metabolism and excretion (ADME) of a chemical that is known to be toxic or whose toxicity is unknown. These studies will also serve to determine the delivered dose to the target organ(s) in order to assess any health hazards using the physiologically based pharmacokinetic (PBPK) modelling. The extrapolation of test results across gender, age, species and doses/exposure may be possible, but requires critical expert judgement to be exercised and explained.

The need for *in vivo* toxicokinetic studies, to determine the processes of absorption, distribution, metabolism and elimination of leachables and degradation products of medical devices, materials and/or their extracts (see 6.2.2.13 and ISO 10993-16), shall be considered in the light of results from the *in vitro* biodegradation studies.

When deciding whether or not to conduct toxicokinetic studies as part of the biological evaluation of a medical device, the final product and its chemical constituents, including potential and designed degradation products and leachables in combination with the intended use of the device, shall all be taken into account (see 6.2.2.13).

Where appropriate, theoretical degradation processes shall be investigated prior to toxicokinetic studies by means of *in vitro* experiments (e.g. tissue, homogenates or cells), not only for animal welfare reasons as given in ISO 10993-2, but also to determine probable rather than possible degradation products.

Toxicokinetic studies shall be considered if

a) the device is designed to be bioresorbable

or

b) the device is a permanent contact implant, and biodegradation or significant corrosion is known or likely, and/or migration of leachables from the device occurs

or

c) substantial quantities of potentially toxic or reactive degradation products and leachables are likely or known to be released from a medical device into the body during clinical use.

Toxicokinetic studies are not required if the achieved or expected rates of release of degradation products and leachables from a particular device or material have been judged to provide safe levels of clinical exposure following reference to significant historical experience, or if sufficient toxicological data or toxicokinetic data relevant to the degradation products and leachables already exist.

The release of leachables and degradation products from metals, alloys and ceramics is usually too low to justify toxicokinetic studies, unless the material is designed to biodegrade.

Toxicokinetic study design for degradation products and leachables is given in ISO 10993-16.

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Immunotoxicology

ISO/TS 10993-20 provides an overview of immunotoxicology with particular reference to the potential immunotoxicity of medical devices. Immunotoxicity testing shall be considered based on the chemical nature of the materials of manufacture and data from sources that are suggestive of immunotoxicological effects or if the immunogenic potential of any of the chemicals is unknown.

Evaluation tests for consideration

Medical device categorization by			Biological effect							
nature of body contact		contact duration (see 5.3) A - limited (u 24 h) B - prolonged (> 24 h to 30 d) C - permanent (> 30 d)								
Category	Contact		Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity (acute)	Subchronic toxicity (subacute toxicity)	Genotoxicity	Implantation	Haemocompatibility
Surface device	Skin	A	X [a]	X	X					
		B	X	X	X					
		C	X	X	X					
	Mucosal membrane	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
	Breached or compromised surface	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
External communicating device	Blood path, indirect	A	X	X	X	X				X
		B	X	X	X	X				X
		C	X	X		X	X	X		X
	Tissue/bone/dentin	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Circulating blood	A	X	X	X	X				X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X
Implant device	Tissue/bone	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Blood	A	X	X	X	X	X		X	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X

[a] The crosses indicate data endpoints that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
3	General principles applying to biological evaluation of medical devices		P
3.1	The selection and evaluation of any material or device intended for use in humans requires a structured programme of assessment.		P
3.2	In the selection of materials to be used in device manufacture, the first consideration should be fitness for purpose with regard to characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological and mechanical properties.		P
3.3	The following should be considered for their relevance to the overall biological evaluation of the device:		--
	a) the material(s) of manufacture;		P
	b) intended additives, process contaminants and residues;		N
	c) leachable substances;		N
	d) degradation products;		P
	e) other components and their interactions in the final product;		P
	f) the properties and characteristics of the final product.		P
3.4	Tests to be used in biological evaluation, and the interpretation of the results of such tests, should take into account the chemical composition of the materials, including the conditions of exposure and the nature, degree, frequency and duration of exposure of the device or its constituents to the body. By following these principles, devices can be categorized to facilitate the selection of appropriate tests (see Clause 4). This part of ISO 10993 is concerned with the tests to be carried out on materials and/or the final product.		P
3.5	All potential biological hazards should be considered for every material and final product, but this does not imply that testing for all potential hazards will be necessary or practical (see Clause 6).		P
3.6	Any in vitro or in vivo tests shall be based on end-use applications and appropriate good laboratory practice followed by evaluation by competent informed persons.		P

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
3.7	The materials or final product shall be considered for biological re-evaluation if change occurs:		P
3.8	The biological evaluation performed in accordance with this part of ISO 10993 should be considered in conjunction with the nature and mobility of the ingredients in the materials used to manufacture the device and other information, other non-clinical tests, clinical studies and post-market experience for an overall assessment.		P
4	Categorization of medical devices		P
4.1	General		P
4.2	Categorization by nature of body contact		P
4.2.1	Non-contact devices		P
	Medical devices that do not contact the patient's body directly or indirectly are not included in the scope of ISO 10993.		P
4.2.2	Surface-contacting devices		P
	These include medical devices in contact with the following surfaces:		--
	a) skin: devices that contact intact skin surfaces only; examples include electrodes, external prostheses, fixation tapes, compression bandages and monitors of various types;		P
	b) mucosal membranes: devices that contact intact mucosal membranes; examples include contact lenses, urinary catheters, intravaginal and intraintestinal devices (stomach tubes, sigmoidoscopes, colonoscopes, gastroscopes), endotracheal tubes, bronchoscopes, dental prostheses, orthodontic devices and intrauterine devices;		N
	c) breached or compromised surfaces: devices that contact breached or otherwise compromised body surfaces; examples include dressings, healing devices and occlusive patches for ulcers, burns and granulation tissue.		N
4.2.3	External communicating devices		N
	These include medical devices in contact with the following application sites:		N

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	a) blood path, indirect: devices that contact the blood path at one point and serve as a conduit for entry into the vascular system; examples include solution administration sets, extension sets, transfer sets and blood administration sets;		N
	b) tissue/bone/dentin: devices that contact tissue, bone or pulp/dentin systems; examples include laparoscopes, arthroscopes, draining systems, dental cements, dental filling materials and skin staples;		N
	c) circulating blood: devices that contact circulating blood; examples include intravascular catheters, temporary pacemaker electrodes, oxygenators, extracorporal oxygenator tubing and accessories, dialysers, dialysis tubing and accessories, haemoadsorbents and immunoadsorbents.		N
4.2.4	Implant devices		N
	These include medical devices in contact with the following application sites:		N
	a) tissue/bone: 1) devices principally contacting bone; examples include orthopaedic pins, plates, replacement joints, bone prostheses, bone cements and intraosseous devices; 2) devices principally contacting tissue and tissue fluid; examples include pacemakers, drug supply devices, neuromuscular sensors and stimulators, replacement tendons, breast implants, artificial larynxes, subperiostal		N
	b) blood: devices principally contacting blood; examples include pacemaker electrodes, artificial arteriovenous fistulae, heart valves, vascular grafts, internal drug-delivery catheters and ventricular assist devices.		N
4.3	Categorization by duration of contact		N
	Medical devices shall be categorized according to the duration of contact as follows:		--
	a) Limited exposure (A): devices whose single or multiple use or contact is likely to be up to 24 h;		N
	b) Prolonged exposure (B): devices whose single, multiple or long-term use or contact is likely to exceed 24 h but not 30 days;		N

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	c) Permanent contact (C): devices whose single, multiple or long-term use or contact exceeds 30 days.		N
5	Testing		P
5.1	General		P
5.2	Initial evaluation tests		P
5.2.1	General		P
5.2.2	Cytotoxicity		P
	With the use of cell culture techniques, these tests determine the lysis of cells (cell death), the inhibition of cell growth, and other effects on cells caused by medical devices, materials and/or their extracts. Cytotoxicity tests are described in ISO 10993-5.		P
5.2.3	Sensitization		P
	These tests estimate, using an appropriate model, the potential of medical devices, materials and/or their extracts for contact sensitization. These tests are appropriate because exposure or contact to even minute amounts of potential leachables can result in allergic or sensitization reactions. Sensitization tests are described in ISO 10993-10.		P
5.2.4	Irritation		P
	These tests estimate the irritation potential of medical devices, materials and/or their extracts, using appropriate sites for implant tissue such as skin, eye and mucous membrane in a suitable model. The test(s) performed should be appropriate for the route (skin, eye, mucosa) and duration of exposure or contact to determine irritant effects of devices, materials and potential leachables. Irritation tests are described in ISO 10993-10.		P
5.2.5	Intracutaneous reactivity		N
	These tests assess the localized reaction of tissue to medical device extracts. These tests are applicable where determination of irritation by dermal or mucosal tests are inappropriate (e.g. medical devices having access to the blood path). These tests may also be useful where extractables are hydrophobic. Intracutaneous reactivity tests are described in ISO 10993-10.		N

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
5.2.6	Systemic toxicity (acute toxicity)		N
	These tests estimate the potential harmful effects of either single or multiple exposures, during a period of less than 24 h, to medical devices, materials and/or their extracts in an animal model. These tests are appropriate where contact allows potential absorption of toxic leachables and degradation products.		N
	Pyrogenicity tests are included to detect material-mediated pyrogenic reactions of extracts of medical devices or materials. No single test can differentiate pyrogenic reactions that are material-mediated from those due to endotoxin contamination. Systemic toxicity tests are described in ISO 10993-11.		N
	Immunotoxicity tests should be considered only for devices where data from other sources is suggestive of immunotoxicological effects.		N
	Systemic toxicity tests may be included in subacute and subchronic toxicity test protocols and implantation test protocols.		N
5.2.7	Subacute and subchronic toxicity		N
	These tests determine the effects of either single or multiple exposures or contact to medical devices, materials and/or their extracts for a period not less than 24 h but not greater than 10 % of the total life-span of the test animal (e.g. up to 90 days in rats). These tests may be waived for materials with chronic toxicity data. The reason for waiving of the tests should be included in the final report. These tests should be appropriate for the route and duration of contact. Subchronic toxicity tests are described in ISO 10993-11.		N
5.2.8	Genotoxicity		N
	These tests use mammalian or non-mammalian cell culture or other techniques to determine gene mutations, changes in chromosome structure and number, and other DNA or gene toxicities caused by medical devices, materials and/or their extracts. Genotoxicity tests are described in ISO 10993-3.		N
5.2.9	Implantation		N

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	These tests assess the local pathological effects on living tissue, at both the gross level and microscopic level, of a sample of a material or final product that is surgically implanted or placed in an implant site or in a tissue appropriate to the intended application (e.g. special dental usage tests). These tests should be appropriate for the route and duration of contact. For a material, these tests are equivalent to subchronic toxicity tests if systemic effects are also investigated. Implantation tests are described in ISO 10993-6.		N
	Implantation test protocols may be expanded to include systemic toxicity tests, subacute and subchronic toxicity tests, and chronic toxicity tests.		N
5.2.10	Haemocompatibility		N
	These tests evaluate, using an appropriate model or system, the effects of blood-contacting medical devices or materials on blood or blood components. Specific haemocompatibility tests may also be designed to simulate the geometry, contact conditions and flow dynamics of the device or material during clinical applications.		N
	Haemolysis tests determine the degree of red blood cell lysis and the release of haemoglobin caused by medical devices, materials and/or their extracts in vitro. Haemocompatibility tests are described in ISO 10993-4.		N
5.3	Supplementary evaluation tests		N
5.3.1	General		N
5.3.2	Chronic toxicity		N
	These tests determine the effects of either single or multiple exposures to medical devices, materials and/or their extracts during at least 10 % of the life-span of the test animal (e.g. more than 90 days in rats). These tests should be appropriate for the route and duration of exposure or contact. Chronic toxicity tests are described in ISO 10993-11.		N
	Chronic toxicity tests may be included in subacute and subchronic toxicity test protocols and implantation test protocols.		N
5.3.3	Carcinogenicity		N

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	These tests determine the tumorigenic potential of medical devices, materials and/or their extracts from either single or multiple exposures or contacts during the major portion of the life-span of the test animal. These tests may be designed in order to examine both chronic toxicity and tumorigenicity in a single experimental study. Carcinogenicity tests should be conducted only if there are suggestive data from other sources. These tests should be appropriate for the route and duration of exposure or contact. Carcinogenicity		N
5.3.4	Reproductive and developmental toxicity		N
	These tests evaluate the potential effects of medical devices, materials and/or their extracts on reproductive function, embryonic development (teratogenicity), and prenatal and early postnatal development. Reproductive/developmental toxicity tests or bioassays should only be conducted when the device has potential impact on the reproductive potential of the subject. The application site of the device should be considered. Reproductive and developmental toxicity tests are		N
5.3.5	Biodegradation		N
	Where the potential for resorption and/or degradation exists, corresponding tests may determine the processes of absorption, distribution, biotransformation and elimination of leachables and degradation products of medical devices, materials and/or their extracts. Biodegradation tests are described in ISO 10993-9.		N
6	Selection of biological evaluation tests		P
	Selection of biological evaluation tests		P
	Evaluation may include both a study of relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design.		P
	Table 1 identifies the initial evaluation tests that shall be considered for each device and duration category. Table 2 identifies the supplementary evaluation tests that shall be considered for each device and duration category.		P

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	Due to the diversity of medical devices, it is recognized that not all tests identified in a category will be necessary or practical for any given device. It is indispensable for testing that each device be considered on its own merits: additional tests not indicated in the table may be necessary.		P
	The tests considered and the rationale for selection and/or waiving of tests shall be recorded.		P
7	Assurance of test methods		P
7.1	Test method assurance		P
	The test methods used in the biological evaluation shall be sensitive, precise and accurate. The test results should be reproducible (interlaboratory) as well as repeatable (intralaboratory).		P
7.2	Continued assurance		P
	The assurance that a material is initially acceptable for its intended use in a medical device, and its continued acceptability in the long term, is an aspect of a quality management system.		P

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**

Table 1 — Initial evaluation tests for consideration

Medical device categorization by			**Biological effect**							
Nature of body contact (see 5.2)		**Contact**								
Category	**Contact**	duration **(see 4.3)** **A— Limited (< 24 h)** **B— prolonged (24 h to 30 days)** **C—** permanent **(> 30 days)**	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity (acute)	Subacute and subchronic toxicity	Genotoxicity	Implantation	Hs mocompatibility
Surface device	Skin	A	x	x	x					
		B	x	x	x					
		C	x	x	x					
	Mucosal membrane	A	x	x	x					
		B	x	x	x					
		C	x	x	x		x	x		
	Breached or Compromised surface	A	x	x	x					
		B	x	x	x					
		C	x	x	x		x	x		
External communicating device	Blood path, indirect	A	x	x	x	x				x
		B	x	x	x	x				x
		C	x	x		x	x	x		x

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EN ISO 10993-1										
Clause	Requirement - Test		Result - Remark							Verdict
	Tissue/bone/dentin	A	x	x	x					
		B	x	x	x	x	x	x	x	
		C	x	x	x	x	x	x	x	
	Circulating blood	A	x	x	x	x				x
		B	x	x	x	x	x	x	x	x
		C	x	x	x	x	x	x	x	x
Implant device	Tissue/bone	A	x	x	x					
		B	x	x	x	x	x	x	x	
		C	x	x	x	x	x	x	x	
	Blood	A	x	x	x	x	x		x	x
		B	x	x	x	x	x	x	x	x
		C	x	x	x	x	x	x	x	x

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Table 2 — Supplementary evaluation tests for consideration						
Medical device categorization by			Biological effect			
Nature of body contact (see 5.2)		Contact duration (see 4.3) A — Limited (< 24 h) B— prolonged (24 h to 30 days) C— permanent (> 30 days)	Chronic toxicity	Carcinogenicity	Reproductive/developmentl	Biodegradation
Category	Contact					
Surface device	Skin	A				
		B				
		C				
	Mucosal membrane	A				
		B				
		C				
	Breached or compromised surface	A				
		B				
		C				
External communicating device	Blood path, indirect	A				
		B				
		C	x	x		
	Tissue/bone/dentin	A				
		B				
		C	x	x		
	Circulating blood	A				
		B				
		C	x	x		
Implant device	Tissue/bone	A				
		B				
		C	x	x		
	Blood	A				
		B				
		C	x	x		

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**

Result:

NITRILE EXAMINATION GLOVE/ LATEX EXAMINATION GLOVE, didn´t cause a skin irritating effect.

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IMAGE

END OF REPORT

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MY Medikal

MY TİCARET VE MEDİKAL A.Ş.

OVERALL MIGRATION TESTING (OMT) REPORT

Type of Glove : Nitrile Powder Free Online Single Chlorinated, Blue, Textured

The test was conducted according to Commission Regulation (EU) No. 10/2011 Requirement for Overall Migration Content (mg/dm^2): $\leq 10 mg/dm^2$.

Type of Stimulant	Size	Testing Condition	Overall migration content requirement	Overall migration result (mg/dm^2)	Disposition
10% Ethanol	S	40^oC, 2 hours	$\leq 10 mg/dm^2$	4.8258	Pass
20% Ethanol				5.3264	Pass
50% Ethanol				8.1565	Pass
10% Ethanol	M			5.3170	Pass
20% Ethanol				4.7831	Pass
50% Ethanol				9.1565	Pass
10% Ethanol	L			5.3264	Pass
20% Ethanol				5.8726	Pass
50% Ethanol				8.9532	Pass

Prepared by,
Z. Melek Öz Bolat
QA/ QC Officer

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad.
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Verified by,
Vedat ÇETİN
QA Engineer

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

JAN,18

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	: Nitrile examination glove [powdered and powder-free]
Chemical Family	: Synthetic nitrile
Company Name	: My Ticaret Ve Medikal A.Ş.
Address	: Ömerli MAh. General Şükrü Koraltı Cad. No:33 Arnavutköy İstanbul- Turkey
Tel	: +90 212 4382065
Fax	: +90 212 4382064

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview

Nitrile examination gloves are not hazardous.

Hazard	: Non-hazardous.
Physical State	: Solid, film.
Colour	: Clear, coloured.

Potential Health Effects

Routes of Exposure	: Skin contact
Signs and Symptoms	: No adverse health effects are anticipated from the reasonable use of nitrile examination gloves.

Eyes	: Non-hazardous.
Inhalation	: Non-hazardous.
Skin	: Not a Primary Skin Irritant. Not a Dermal Sensitizer.
Ingestion	: This product has not been tested.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Powdered	: Nitrile Latex, Stabilizer, Surfactant (SDBS), Accelerator, Cross Linking Agent, Activating Agent, Pigment
Powder-Free	: Nitrile Latex, Stabilizer, Surfactant (SDBS), Accelerator, Cross Linking Agent, Activating Agent, Pigment

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

JAN,18

SECTION 4: FIRST AID MEASURES

Steps to be taken in event of mishap:

Eyes	: Non-applicable.
Inhalation	: Non-applicable.
Skin	: Wash with soap and water.
Ingestion	: Seek medical attention if a significant quantity has been swallowed.

SECTION 5: FIRE FIGHTING MEASURES

Flammability Classification	: Non-classified. Gloves will burn but do not easily ignite.
Extinguishing Media	: Water spray, carbon dioxide, foam or dry chemical.
Firefighting Precautions	: Wear self-contained breathing apparatus and full fire-fighting turn-out gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Release Response	: Retain for recycle or disposal.

SECTION 7 : HANDLING AND STORAGE

Nitrile examination gloves shall maintain their properties when stored in dry condition at temperature between 10°C to 30°C. Protect gloves against ultraviolet light sources such as sunlight and oxidizing agents.

SECTION 8: EXPOSE CONTROLS AND PERSONAL PROTECTION

Engineering Control

Use local exhaust in confined spaces where nitrile examination gloves are heated.

Personal Protective Equipment

Eyes	: Not required. Use goggles if nitrile examination gloves are heated.
Inhalation	: Not required.
Skin	: Not required. Use heat resistant gloves if nitrile examination gloves are heated to melting state.

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

JAN,18

SECTION 9: PHYSICAL/ CHEMICAL PROPERTIES

Appearance	: Ambidextrous, textured and clear or colored
Physical State	: Solid
Odour	: Odourless
pH	: 7.35

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	:	Nitrile examaination gloves.
Conditions to Avoid	:	Avoid contact with excessive heat, sparks or open flame. Avoid dust accumulation.
Hazardous Products	:	Variety of toxic off-gases may be formed when nitrile examination of decomposition gloves burn and may further cause respiratory irritation.

The gloves shall have shelf life of 5 years from the date of manufacturer with the above storage condition.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Effects	: Non-toxic.
Sub-chronic and Chronic Effects	: Non-toxic.

SECTION 12: ECOLOGICAL INFORMATION

Product of Biodegradation	: Non-biodegradable.
Ecotoxicity	: Nitrile examination gloves are considered as inert.

SECTION 13: DISPOSAL CONSIDERATION

This document covers the recommended method for disposal for nitrile examination gloves manufactured by My Ticaret Ve Medikal A.Ş.

Incineration: Put appropriate amount of the gloves into the incinerator or furnace to destroy them following the requirements shown below.

Requirements:

1) Burning temperature exceeds 850°C
2) Combustion retention time is not less than 2 seconds

Note: Gloves should not be destroyed by open burning at low temperature or dispose at normal disposal area.

Other Disposal Considerations : Check with state and local authorities before discarding. The information offered here is for product as shipped. Use and/or alterations to the product such as mixing with other materials may significantly change the characteristics of the material and alter the proper disposal method.

SECTION 14: TRANSPORT INFORMATION

Non-dangerous goods.

SECTION 15: REGULATORY INFORMATION

Non-applicable.

SECTION 16: OTHER INFORMATION

This Product Safety Data Sheet is offered solely for your information. My Ticaret Ve Medikal A.Ş. provides no warranties, either express or implied, concerning the sage use of this product in your process or in combination with other substances and assumes no responsibility for the accuracy or completeness of the data contained herein. User has the sole responsibility to determine the suitability of the product for any use and the manner of use contemplated.

……END……...

Prepared By:
QA/ RA Division

Verified By:
Vedat Çetin
QA Manager